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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,970	11/21/2006	Jonathan Edward Creeth	CB60508	4572

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GlaxoSmithKline
GLOBAL PATENTS -US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
11/23/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com
arlene.e.cannon@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/572,970	CREETH, JONATHAN EDWARD	
	Examiner	Art Unit	
	SNIGDHA MAEWALL	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *21 and 22* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *21 and 22* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Previous Rejections

Applicants' arguments, filed 09/19/11 have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 21-22 are objected to for not being in compliance with 37 CFR 1.121(c)(2). There are single brackets present in claim 21 and claim 22 (around the "consisting of" for example). These appear to be attempts at deletion. However, double brackets, not single brackets, are used to denote deletions, and only when five or fewer characters are deleted. See 37 CFR 1.121(c)(2). In the interest of compact prosecution, the amendment is being considered. Applicant is urged to verify that any future amendment is fully compliant with 37 CFR 1.121 in order to avoid any unnecessary delays in prosecution on the merits.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is a "new matter" rejection. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claims 21 to 22 recite the limitation "wherein no silver ions are present". Recourse to the instant specification does not reveal disclosure of such limitations. This is a new matter rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over (European Publication No. EP 000002184, abstract and Machine translation of record).

EP 000002184 teaches fine granules of polyphosphate of the general formula $Na_n+2P_nO3_n=1$ in which n>/=3 and are used for rapid elimination of tartar and /or tooth discoloration in smokers and also act as activity strengthener for dental cleaning

products, abstract (In the above formula of polyphosphate, in the instances where n are greater than 3 that are 5, the formula will read on pentasodium polyphosphate as claimed in instant claim 21). EP 000002184 teaches use of complexing agent sodium polyphosphate and the amount from 2 to 5%, (page 1 of translation and second paragraph), (sodium polyphosphate reads on calcium sequestering agent as claimed in instant claims 21 to 22. The amount of 2 to 5% sodium polyphosphate reads on the claimed range of 1-20% sodium polyphosphate.

The reference does not include silica abrasive in the formulation and no silver ions are disclosed to be used in the reference.

EP 000002184 does not teach the claimed RDA/IVSR values; however, since the amount of sodium polyphosphate overlaps with the claimed amount and there is no presence of any other abrasive, it is reasonable to conclude that the property of the composition would possess the RDA and IVSR values substantially similar to the claimed value absent evidence to contrary. The RDA is a measure of abrasiveness, and the lack of an abrasive would provide a low RDA value (such as about 10 - see table 5 of the instant specification). And IVSR is a measure of cleaning (stain removal) and appears to be controlled by the sodium polyphosphate (table 5 of the instant specification). As '184 discloses using the polyphosphate in amounts that read on the amounts recited, and this ingredient appears to provide the recited IVSR value, it appears reasonable to conclude the taught compositions possess an IVSR value that reads on the limitation recited.

Additionally, it is to be noted that instant specification discloses on page 3, lines 10-14 that EP-A-0 002 184 discloses the use of a sodium polyphosphate in fine granulate form for tooth cleaning, either by itself or in combination with a commercial toothpaste formulation, referring to the abrasive effect of the sodium polyphosphate and intensification of tooth cleaning by this material **without damaging** the substance of the teeth. Therefore in light of above, it is Examiner's position that since no damage to teeth was done by using EP's formulation, one would expect RDA values to be low because it is known in the art that high RDA value provides damage to tooth dentin).

In regards to the claimed limitation that "the composition has an RDA value of below 30 and an IVSR value greater than 50, when compared to a Control dentifrice containing 14% Zeodent 113 abrasive silica in a conventional base containing water, sorbitol, glycerin, PEG, flavor, sodium lauryl sulphate, sodium saccharin, xanthan gum and sodium fluoride as recited in instant claim 22, it is reasonable to conclude that since EP does not disclose using abrasive such as 14% Zeodent 113 or any other abrasive and teaches inclusion of pentasodium polyphosphate for dental cleaning and color removing properties and since the amount of 2 to 5% sodium polyphosphate reads on the claimed amount , one of ordinary skill would expect the RDA and IVSR values to be substantially similar to the claimed one.

Applicant's arguments:

Applicant argues with respect to the EP reference that instant example 1 of the disclosure teaches surprising results when compared with the commercially available

dentifrices containing 14% abrasive Zeodent 113 and the surprising results show that an abrasive is not actually needed for cleaning at a level broadly comparable with that of a conventional silica abrasive toothpaste formulation such as the Control. On pages 2 to 6, applicant shows comparative data among various formulations and contends that instantly claimed formulation 599 provides RDA value less than 30 and IVSR value more than 50 where as other formulations comprising abrasive such as Zeodent 113 along with sodium polyphosphate provide higher RDA value.

Applicant's arguments are not persuasive. While it is true that instantly claimed formulation 599 disclosed on page 4 of arguments, provides RDA value less than 30 and IVSR value more than 50 where as other formulations comprising abrasive such as Zeodent 113 along with sodium polyphosphate provide higher RDA value, it is respectfully pointed out that since EP does not disclose using abrasive such as 14% Zeodent 113 or any other abrasive and teaches inclusion of pentasodium polyphosphate for dental cleaning and color removing properties in an amount that reads on the amount as claimed instantly, one of ordinary skill would expect the RDA and IVSR values to be substantially similar to the claimed one and thus the surprising or unexpected results are really not unexpected in light of the teachings of EP's reference. Additionally, instant claim 21 recites the amount of sodium polyphosphate from 1% to 20%, however, the results are shown only with formulation comprising 10% amount of sodium polyphosphate, the results therefore, do not commensurate with the entire scope of instant claims. The surprising results shown by applicants in formulation 599 versus other formulations is mainly by excluding abrasive silica such as Zeodent 113

abrasive, however, the limitations of using 0-2 wt. % abrasive in instant claim 21 reads on any abrasive such as amorphous or precipitated silica which are known in the art to possess low RDA values. The results therefore do not commensurate with the entire scope of the claimed invention.

Applicant further argues that there are no formulation examples in EPA 0002184, only two "application" examples at the end of the document that show that the "polyphosphate fine granulate" is used in conjunction with a conventional toothpaste. Applicant adds that EPA 0002184 very clearly discloses that the conventional toothpastes are "designed for average requirements" and therefore, one of skill in the art would have to assume that the abrasive levels are typical of average toothpaste. According to Applicant this would mean that the abrasive levels in the formulation would on average be somewhere between 10-15%w/w.

Applicant's arguments are not persuasive as applicant's themselves disclose in the instant specification on page 3, lines 10-14 that "EP-A-0 002 184 discloses the use of a sodium polyphosphate in fine granulate form for tooth cleaning, **either by itself** or in combination with a commercial toothpaste formulation, referring to the abrasive effect of the sodium polyphosphate and intensification of tooth cleaning by this material **without damaging** the substance of the teeth".

Therefore, in light of above, it is reasonable to conclude that EP does contemplate making dentifrice formulation with only sodium polyphosphate without any further use of abrasive (that is without combining with conventional tooth paste formulation comprising high amount of abrasive) and such a formulation will exhibit low

RDA value and good cleaning properties. In response to applicant's arguments that EP provides only two "application" examples at the end of the document that show that the "polyphosphate fine granulate" is used in conjunction with a conventional toothpaste, it is respectfully pointed that the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Additionally, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi,* 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In the instant case while the reference discloses using conventional tooth paste in conjunction with EP's formulation; however the reference does disclose using EP's formulation by itself as is admitted by applicants themselves as discussed above).

Applicant then refers to US 4,996,042 (Wagner) in which there is a disclosure in column 2, line 35, that the proportion of polishing agents is between 20-60% by weight of the total composition. Therefore the compositions disclosed in EPA 0002184 will contain abrasive levels on the order of 10-15%w/w which would not give RDA values of less than 30, as required in the claimed invention.

Applicant's arguments regarding Wagner's teachings of using high RDA abrasives in dentifrice is not persuasive because the reference does not demonstrate

that one of ordinary skill must have included abrasives in every toothpaste, or the specific compositions discloses by EP-A-0 002 184.

Claims 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over (European Publication No. EP 000002184, abstract and Machine translation of record) as applied to claim 21 above, and further in view of NAKAO et al. (Japanese Patent Publication (2003-073245)).

EP 000002184 as discussed above does not teach the use of abrasive silica with an RDA below 30 as recited in instant claim 22.

NAKAO discloses composition for oral cavity. The dentifrice composition scarcely damages and abrades dentin and has high stain –removing effect, abstract. NAKAO teaches use of precipitated silica with an RDA value of <=70, (page 1 of the reference attached).(it is to be noted that less than 70 reads on any value that is less than 70 and thus reads on the claimed RDA value of less than 30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated precipitated silica in the dentifrice composition of EP 000002184 in order to have added effect of color/stain removing properties motivated by the teachings of NAKAO et al. Since the composition of EP and NAKAO, both are directed to the color/stain removing dentifrice, one of ordinary would have been motivated to use precipitated silica with low RDA as taught by NAKAO to be used in combination with sodium polyphosphate of EP with an expectation to obtain added

stain-removing effect as taught by NAKAO due to precipitated silica with an added advantage of having a composition with reduced dentin abrasion.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612